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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,264	10/27/2003	Geoffrey A. Russell	112455-145568	2808

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EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/694,264	RUSSELL ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 26-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 26-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This is a final Office action. Any new grounds of rejection were necessitated by the applicants' amendments to the claims.

Claim Objections

Claims 1, 30, 31 and 34-36 are objected to because of the following informalities:

On line 1 of step c of claim 1, "fluids" should be replaced with "fluid";

On lines 1-2 of claim 30, further comprising removing said analyte sensing element" should be replaced with "wherein, in step (d), said analyte sensing element is removed";

On lines 1-2 of claim 31, "further comprising removing said analyte sensing element" should be replaced with "wherein, in step (d), said analyte sensing element is removed"

There are two claims with the claim number "34". The second claim "34" should be replaced with claim number "35" and claims 35 and 36 should likewise be renumbered as claims "36" and "37". For the purposes of examination the claims will be referred to by this corrected claim numbering rather than by the claim numbers as they appear in the claims filed 11/18/05.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 37 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 36 recites, "the absorbent layer being adapted to facilitate the covered analyte sensing element to be introduced into contact with soft tissue of an animal body" on lines 5-7 of the claim. The specification lacks sufficient description of how the absorbent layer facilitates such introduction as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 26, and 32 are rejected under 35 U.S.C. 102(b) as anticipated by US Patent No. 5,820,622 to Gross. Gross teaches a method of measuring an analyte concentration in body fluid having skin and subcutaneous soft tissue that includes body fluid. An analyte measuring device is provided, the device including an analyte sensing element 52 having a sharpened distal end 55 to facilitate introduction into the animal body and further having an indicating electrode 23,55 covered by an absorbent layer 28,

wherein a perfluorinated ion-exchange membrane such as Nafion® is an absorbent material (figs. 1 & 8; col. 15, lines 15-40; col. 17, lines 48-61 of Gross; see col. 2, lines 48-52 of US Patent No. 5,181,995 to Kummer for teaching of perfluorinated ion exchange material such as Nafion ® being an absorbent material). The analyte measuring device also includes an electric power, data processing and display device 53 adapted to mate to the sensing element, activate the element by applying electric power to it and to receive the raw analyte measurement to compute and display a refined analyte measurement (col. 15, line 42-col. 16, line 3; col. 17, line 64-col. 18, line 51 of Gross). The sensing element is introduced into the subcutaneous soft tissue, thereby placing the absorbent layer into contact with the animal body subcutaneous soft tissue and body fluid (col. 15, lines 27-50 of Gross). The element is activated by applying electric power, thereby causing the formation of a raw analyte measurement, and the electric power, data processing, and display device receives the raw analyte measurement and computes and displays a refined analyte measurement related to the raw analyte measurement.

Gross fails to explicitly state that the absorbent layer 28 becomes saturated with body fluid. However, since Gross discloses producing an indication of glucose concentration based on the enzymatic oxidation of glucose, which cannot be performed unless the body fluid passes through the absorbent layer 28, it is inherent that the absorbent layer 28 must become saturated before the body fluid can reach the glucose oxidase enzyme coating 27. Similarly, while Gross fails to explicitly recite removing the indicating electrode from the body soft tissue, the reference states that the electrodes,

including indicating electrode 55 are replaced. In order to replace the electrode 55, it must inherently be removed from the body.

It is noted that, in the description of the embodiment of figs. 8-11 of Gross, the working electrode 55 is described as " a platinum-iridium needle coated with a glucose oxidase enzyme coating, as previously described" (col. 17, lines 59-61 of Gross). As previously described, such an electrode also includes a layer of absorbent material (col. 15, lines 15-30 of Gross).

Regarding claim 26, the enzyme layer 27 is interposed between the indicating electrode 23, 55 and the absorbent layer 28 (fig. 2; col. 15, lines 15-30; col. 17, lines 59-61 of Gross).

Regarding claim 32, Gross teaches a method of measuring an analyte concentration in body fluid in an animal body. An analyte sensing element is provided having an indicating electrode 23 covered by an absorbent layer 28 forming an exterior surface of the element, wherein a perfluorinated ion-exchange membrane such as Nafion® is an absorbent material (figs. 1 & 2; col. 8, lines 23-29; col. 15, lines 17-52 of Gross). The analyte sensing element is introduced into soft tissue of the body thereby placing the absorbent layer 28 in contact with the animal body soft tissue and body fluid (col. 15, lines 31-45 of Gross). The analyte sensing element is activated, thereby causing the element to form an analyte measurement (col. 15, lines 44-56 of Gross) which measurement is received by the microprocessor (Col. 15, line 65-col. 16, line 13 of Gross).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gross, as applied to claims 1 and 26 above, and further in view of US Patent No. 4,953,552 to DeMarzo. Gross lacks a redox mediator layer interposed between the enzyme layer and the indicating electrode. However, DeMarzo discloses an analyte sensing element configured to be inserted into the skin and soft tissue of a user. The sensing element comprises a redox mediator layer 68 interposed between the enzyme layer 70 and the electrode 54 (fig. 5; col. 4, lines 4-10 of DeMarzo). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the element of DeMarzo with that of Gross in order to immobilize the enzyme on the electrode (col. 4, lines 9-10 of DeMarzo).

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gross, as applied to claims 1 and 26 above, and further in view of US Patent No. 6,083,710 to Heller. Gross lacks a permselective layer between the enzyme and the absorbent layers. However, Heller discloses an analyte sensing element comprising a permselective layer 10 interposed between the enzyme layer 8 and the absorbent layer 14 (fig. 1; col. 4, lines 16-23; col. 5, lines 47-55; col. 6, lines 16-24 of Heller). Therefore,

it would have been obvious to one of ordinary skill in the art to combine the element of Heller with the method of Gross in order to provide more accurate analyte measurements (col. 3, lines 7-16; col. 5, lines 48-50 of Heller).

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gross, as applied to claims 1 and 26 above, and further in view of Heller. Gross lacks an interferent excluding layer between the enzyme and absorbent layers. However, Heller discloses an analyte sensing element comprising an interferent excluding layer 12 interposed between an enzyme layer 8 and an absorbent layer 14 (fig. 1; col. 4, lines 15-23; col. 5, line 62-col. 6, line 24 of Heller). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the element of Heller with the method of Gross in order to make one-point in vivo calibration of the sensor possible (col. 3, liens 16-18 of Heller).

Claims 1, 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication No. 2003/0223906 to McAllister et al. in view of US Patent No. 5, 820, 622 to Gross. McAllister teaches a method of measuring an analyte concentration in body fluid in an animal body having skin and subcutaneous soft tissue that includes body fluid, wherein an analyte measuring device is provided. The device includes an analyte sensing element 2 having a sharpened distal end 4 to facilitate introduction into the animal body and further having an indicating electrode (figs. 1 & 3; paragraphs 41-43, 49, 70, 71 of McAllister). The device also includes an electric power,

data processing and display device 6 adapted to mate to the analyte sensing element 2, activate the analyte sensing element 2 by applying electric power to it, and receive the raw analyte measurement and to compute and display a refined analyte measurement, related to the raw analyte measurement (fig. 1; paragraphs 49-52, 55, 65, 66 of McAllister). The analyte sensing element 2 is introduced into the animal body subcutaneous soft tissue, thereby placing the sensing element 2in contact with the subcutaneous soft tissue and body fluid (paragraph 51 of McAllister). The sensing element 2 is permitted to collect sufficient sample and then is removed from the body soft tissue. The analyte sensing element 2 is activated by applying electric power to it, thereby causing the analyte sensing element 2 to form a raw analyte measurement. The electric power, data processing, and display device 6 receives the raw measurement and computes and displays a refined analyte measurement related to the raw measurement (paragraphs 43, 52, 55, 65-67 of McAllister). McAllister teaches that a hydrophilic agent may form an exterior surface of an analyte sensing element (paragraphs 43 & 77 of McAllister) but lacks reciting an absorbent material.

However, Gross teaches a method and apparatus for determining the analyte concentration in an animal body wherein the analyte sensing element includes an indicating electrode covered by an absorbent layer (fig. 2; col. 15, lines12-52 of Gross), wherein a perfluorinated ion exchange membrane, such as Nafion® is hydrophilic and absorbent (see col.2, lines 48-52 of US Patent No. 5,181,995 to Kummer for a teaching of a perfluorinated exchange material such as Nafion ® being absorbent; see col. 5, lines 14-20 of Kummer for teaching of same material being hydrophilic). Therefore, it

would have been obvious to one of ordinary skill in the art at the time of invention to use a perfluorinated ion exchange membrane of Gross as the hydrophilic agent in the method of McAllister since McAllister teaches using a hydrophilic agent and Gross discloses a perfluorinated ion exchange membrane as an appropriate such agent in an analyte sensor. It would similarly have been obvious to use the perfluorinated ion exchange membrane as forming an exterior surface of the sensing element in the method of McAllister to protect the enzyme before and during the use of the device (col. 8, lines 23-29 of Gross).

Regarding claims 30, 31, 35, and 36, the analyte sensing element may be removed from the animal body within about 20 seconds or within about 5 seconds of being introduced into the body (paragraph 59 of McAllister).

Regarding claim 33, the analyte sensing element is removed from the body prior to activating the analyte sensing element (paragraph 65 of McAllister).

Regarding claim 34, if the absorbent layer covers the indicating electrode (fig. 2 of Gross; paragraphs 43 & 77 of McAllister), then the absorbent layer must inherently be saturated before the body fluid reaches the enzyme or indicating electrode in order to produce an analyte concentration signal.

Response to Arguments

Applicant's arguments with respect to claims 1 and 26-29 have been considered but are moot in view of the new ground(s) of rejection.

It is noted that the applicants remark on p. 7 of the response filed 11/18/05 that claim 1 recites removal prior to activation of the sensing element. However, claim 1 contains no such limitation. While the step (e) of activating the analyte sensing element appears in the body of the claim before step (d) of removing the indicating electrode, the mere order of the appearance of steps in the body of the claim fails to impose a specific order on the performance of steps. If the applicants intend to impose such an order in the performance of steps in the method of claim 1, the claim language should explicitly reflect that order.

Allowable Subject Matter

Claim 37 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter: Regarding claim 37, the prior art of record fails to teach or fairly suggest a method comprising covering the analyte sensing element with an absorbent layer, forming an exterior surface of the analyte sensing element, with the absorbent layer being adapted to facilitate the covered analyte sensing element to be introduced into contact with soft tissue of an animal body, in combination with all of the other limitations of the claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari
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Art Unit 3736